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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/081,736

02/20/2002

Justin R. Fallon

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EXAMINER

CHERNYSHEV, OLGA N

ART UNIT

PAPER NUMBER

1649

MAIL DATE

DELIVERY MODE

05/24/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/081,736	Applicant(s) FALLON ET AL.	
	Examiner Olga N. Chernyshev	Art Unit 1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 April 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13, 16, 32 and 34-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13, 16, 32 and 34-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Claim 13 has been amended as requested in the amendment filed on April 19, 2007.
Following the amendment, claims 13, 16, 32 and 34-39 are pending in the instant application.
Claims 13, 16, 32 and 34-39 are under examination in the instant office action.
2. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.
3. Applicant's arguments filed on April 19, 2007 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 13, 16, 32 and 34-38, as amended, stand rejected under 35 U.S.C. 102(b) as being anticipated by Ruoslahti et al., US Patent No. 5,654,270 for reasons of record in previous communications of record.

At p. 4 of the Response, Applicant submits that “the specification amply teaches the use of biglycan therapeutic in treating disorders including conditions associated with defective clustering of acetylcholine receptor (AChR)” and refers to the specific pages for support of the amendment to claim 13, which now recites “wherein the cell exhibits defective clustering of

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acetylcholine receptor (AChR)". Applicant further argues that "the Examiner has provided no evidence or reasoning that cells which exhibit defective clustering of AChR were included in the methods of Ruoslahti et al." (p. 6 of the Response). Applicant's arguments have been fully considered but are not persuasive for the following reasons.

The instant claims 13, 16, 32 and 34-38 encompass a method for activating a membrane of a cell by contacting the cell with a biglycan therapeutic. The claims do not require that the cell is of a specific origin or type and, as such, as fully explained earlier in the previous communications of record, the patent of Ruoslahti et al., which expressly describes contacting biglycan with the cells fully meets all the limitations of the claims. The newly presented limitation "wherein the cell exhibits defective clustering of acetylcholine receptor (AChR)" appears to limit the scope of the claims only to the cells, which derive from biglycan deficient mice because it appears to be the only condition where the myotube cells exhibit defective agrin-induced AchR clustering (p. 12 of the instant specification). Furthermore, the diseases that are "associated with abnormal cytoplasmic membrane", which includes "abnormal AchR aggregation", encompass wounded tissue, which was treated by administration of biglycan in the Ruoslahti et al. patent.

Applicant is advised that because biglycan therapeutic has been shown to have a biphasic effect on cell activation (Example 10, p. 83), including the concentration range, which enables practicing the instant method, would distinguish the instant claims and the prior art of record.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 13, 16, 32 and 34-39 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claim 13, as amended is vague and indefinite for recitation “wherein the cell exhibits defective clustering of acetylcholine receptor (AChR)”. Since the term “defective clustering of AChR” is not clearly defined in the art of record and because the instant specification only describes pathological argin-induced clustering of AChR in myotubes derived from transgenic mice, the instant newly presented limitation is vague and ambiguous. Because there is no criteria known in the art or fully disclosed in the instant specification, as filed, as how to ascertain the defectiveness of AChR clustering, a skilled artisan cannot determine if a method of contacting biglycan with a cell which meets all of the other limitations of a claim would then be included or excluded from the claimed subject matter by the presence of this limitation.

9. Claims 16, 32 and 34-39 are indefinite for being dependent from indefinite claim.

Conclusion

10. No claim is allowed.

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Olga N. Chernyshev, Ph.D.

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Primary Examiner
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May 23, 2007